

REMARKS

By this Reply, Applicant proposes to amend claims 1, 2, 5, 6, 9, 13, 37, 50, and 52. Accordingly, claims 1-13, 15-19, 21-26, 28-32, 34, 35, 37-39 and 41-52 will be pending in this application when this Reply is entered. No new matter has been added. Applicant requests the prompt reconsideration and allowance of this application.

In the Office Action dated October 14, 2010 (the Office Action), claims 1-4, 6, 7, 11-13, 15-17, 21-26, 28, 300-32, 34, 35, 37-39, 41, 44, and 50-52 were rejected under 35 USC §102(b) as being anticipated by US Patent No. 5,391,381 to Wong et al. (Wong). Applicant respectfully traverses this rejection.

Wong discloses several different embodiments of a dispenser capable of delivery a plurality of drug units. The rejection set forth in the Office Action characterizes several different embodiments as allegedly meeting the features of the rejected claims. For example, the embodiment of Fig. 7 is relied upon to allegedly disclose a film thinner than the base and skirt wall and disposed within an opening of the cavity, extending the length of the cavity effectively closing it. Office Action at pg. 4. The embodiments of Figs. 11-12 are relied upon to allegedly teach first and second mouth openings that interlock and that are held together with an ultrasonic weld. Id. The embodiments of Figs. 9-13 are relied upon to allegedly teach a plug and socket arrangement. Id.

None of these embodiments, however, disclose or suggest a film that is attached to a rim outside of a cavity and closing the cavity. Wong generally describes the apparatus and explains the function of the several different embodiments of the dispenser with reference to the embodiment of Fig. 1. As described in Wong, the embodiment of Fig. 1 includes a housing 20 having an exit port 22 and a plurality of movable discrete units 24, 26, 28, 30, and 32. Wong at col. 5, ll. 52-56. The dispensing

unit further includes a driving member 34 that operates to displace the units toward and through the exit port 22. *Id.* at ll. 3-65. In an attempt to meet the features of the claims, the rejection characterizes element 124 of the embodiment of Fig. 7 as a "film." Wong at col. 13, ll. 7-27. The rejection seemingly further characterizes the partitions 146, 148, 150, 152 and 154 of the embodiment of Fig. 8, and similar partitions or layers in Figs. 9 and 10, such as layer 176, as "films." Similar to element 124 in the embodiment of Fig. 7, these partitions or layers are disposed within the respective housings, , and not outside. See Wong at col. 13, ll. 61-68; col. 14, ll. 64-66; col. 15, ll. 27-30. The embodiments of Figs. 11-15 have similar layers or partitions disposed within, and not outside, the respective housing. See e.g., Wong at Figs. 7-15. The rejection does not specifically explain how Wong seemingly discloses the characterized films as being outside of a cavity. In fact, the rejection specifically states that with respect to the embodiment of Fig 7, "the film . . . is disposed **within** [the] opening of the cavity." Office Action at pg. 4. (emphasis added).

For at least these reasons, Applicant submits that Wong does not anticipate the claims. Wong fails to disclose a film that is attached to a rim outside of a cavity and closing the cavity. The exit port of the several embodiments of Wong is open, and thus does not close a cavity, and the layers or partitions separating drug units are disposed within the housing, and thus not outside a cavity. Applicant submits that claims 1-4, 6, 7, 11-13, 15-17, 21-26, 28, 30-32, 34, 35, 37-39, 41, 44, and 50-52 are allowable for at least these reasons.

In the Office Action claims 1, 15, 16, 18, 19, and 29 were rejected under 35 USC §§ 102(a) and 102(e) as being anticipated by US Patent No. 7,163,693 to Clarke et al.

(Clarke). Applicant respectfully traverses this rejection, at least with respect to the claims as proposed to be amended herein.

Applicant does not necessarily concede that previously presented independent claim 1 is anticipated by Clarke. Nonetheless, Applicant proposes to amend independent claim 1 in an effort to advance prosecution to recite that the first film is disposed substantially planar relative to the first mouth opening. The rejection set forth in the Office Action characterizes parts 62 and 64 as "film coatings." Office Action at pg. 3. Clarke describes parts 62 and 64 as capsule compartments "forming an open ended 'bucket' or 'tub' shape." Clarke at col. 18, ll. 4-9. Accordingly, Applicant submits that independent claim 1 and dependent claims 15, 16, 18, 19, and 29 are allowable for at least these reasons.

In the Office Action claims 1, 2, 5, 6, 8-10, 42, 43, 50, and 52 were rejected under 35 USC 102(b) as being anticipated by US Patent No. 4,324,338 by Beall (Beall). Applicant respectfully traverses this rejection.

Beall discloses a container that is described in numerous instances throughout the specification as being used in conjunction with administering the sacramental elements during communion services. See e.g., Beall at Abstract. Merely because Beall mentions that the containing can also be used for administering medication in the Abstract and in column 5, lines 43-63, does not establish the disclosed container of Beall as a pharmaceutical dosage form for selectively releasing a drug substance to provide a controlled drug release profile in a gastrointestinal environment. Taken as a whole, one of ordinary skill in the art would understand that Beall discloses a container that is not a dosage form. See e.g., Beall at col. 1, ll. 5-8 (the container is "conveniently

adaptable for holding and dispensing the sacramental elements of bread and wine in a quick, orderly fashion to an individual or to members of a congregation during a communion service"); col. 2, ll. 26-30 (The present device is comprised of a cup-like compartment which is generally cylindrical in shape and adaptable to hold a liquid therein and preferably has its upper end flared outwardly so as to aid users in drinking"); col. 2, ll. 59-63 ("It is therefore a principal object of the present invention to provide a simple compartmented container capable of being used to efficiently and expeditiously dispense both a liquid and a non-liquid substance such as to a large group during the communion service"). Applicant respectfully submits that it is unreasonable and in contradiction to MPEP § 2111 to interpret the claims that recite a "pharmaceutical dosage form for retaining and selectively releasing a drug substance to provide a controlled drug release profile in a gastrointestinal environment" such that the disclosure of Beall allegedly anticipates them.

Although, Applicant does not concede that Beall anticipates claims 1, 2, 5, 6, 8-10, 42, 43, 50, and 52 for at least the reasons set forth above, Applicant proposes to amend claims 1, 5, 6, 9, 50, and 52 to more clearly define the claimed dosage forms, in an effort to advance prosecution. For example, independent claim 1 has been amended to recite at least one of the first film, the body, or an attachment between the first film and the first rim is configured to dissolve or otherwise breach within the gastrointestinal environment to expose the at least one cavity to the gastrointestinal environment. Similar amendments have been made to independent claims 5, 6, 9, 50, and 52. Accordingly, Applicant submits that claims 1, 2, 5, 6, 8-10, 42, 43, 50, and 52 are allowable for at least these reasons.

Applicant respectfully requests that this Reply under 37 C.F.R. § 1.116 be entered by the Examiner, placing the pending claims in condition for allowance. Applicant submits that the proposed amendments to the claims do not raise new issues nor necessitate the undertaking of any additional search of the art by the Examiner. Therefore, this Reply should allow for immediate action by the Examiner.

Furthermore, Applicant respectfully points out that the final Office Action by the Examiner applied new grounds of rejection against the claims and presented new arguments as to the application of the art against Applicant's invention. It is respectfully submitted that the entering of this Reply would allow the Applicant to reply to the final rejections and place the application in condition for allowance.

Finally, Applicant submits that the entry of the amendments would place the application in better form for appeal, should the Examiner still dispute the patentability of the pending claims.

In view of the foregoing remarks, Applicant submits that this claimed invention, at least as amended, is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicant therefore requests the entry of this Reply, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.


If the Examiner believes a telephone conversation might advance prosecution, the Examiner is invited to call Applicant's undersigned representative at 202-408-4397.

Please grant any extensions of time required to enter this response and charge
any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

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Dated: December 14, 2010

By: 

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